

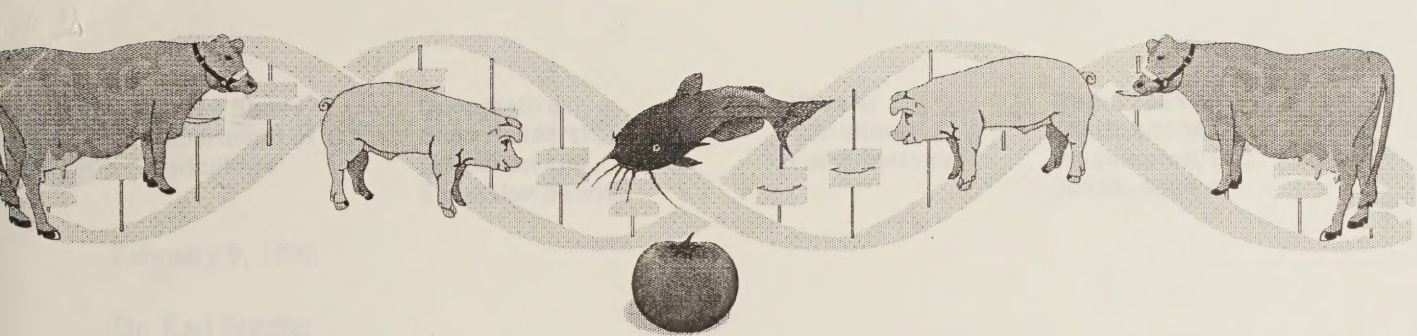
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**United States
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FINAL REPORT

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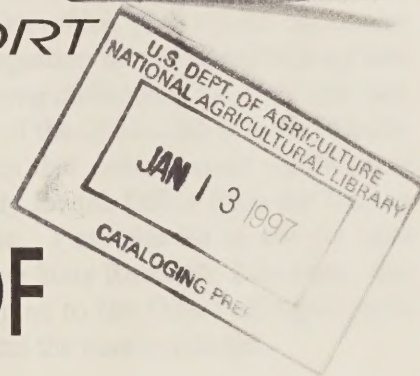
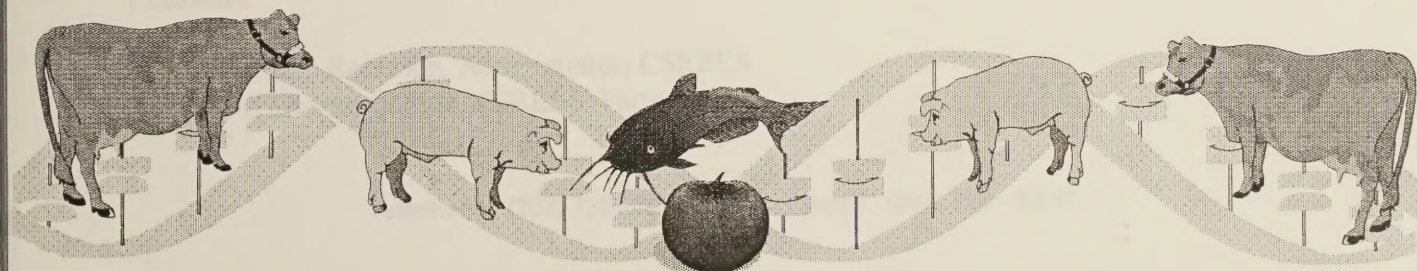
WORKING TO

OFFICE OF

AGRICULTURAL BIOTECHNOLOGY

November 1987 - February 1996

United States Department of Agriculture
Washington, DC



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United States
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Cooperative
State Research,
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Extension Service

Office of
Agricultural
Biotechnology

Room 3868-S
AG Box 0904
Washington, D.C.
20250-0904

February 9, 1996

Dr. Karl Stauber
Under Secretary
Research, Education, and Economics

Dear Dr. Stauber,

It is with pleasure that I submit to you the Final Report of the Office of Agricultural Biotechnology. Secretary Richard Lyng offered me the opportunity of coming to USDA as a detailee from the Department of Defense in November 1987 and establishing an office that would harmonize relationships between agencies and provide direction to the integration of a new technology into USDA's research, education, and regulatory programs. Secretary Lyng challenged me to do that task within ten years. In 1989, Secretary Yeuter appointed me Director of the Office and Science Advisor (atch) and reiterate the need to have a comprehensive program that encompassed all facets of biotechnology. Secretary Yeuter, also transferred responsibility for the Office from the Deputy Secretary to the Assistant Secretary for Science and Education. I am pleased to say we have accomplished our mission. I want to thank you and the Cooperative State Research, Education, and Extension Service for the outstanding direction and support given to the Office of Agricultural Biotechnology. CSREES has provided the financial resources and the core personnel.

As I leave this mission responsibility, I would like to make three recommendations: (1) that the Biotechnology Information Center at the National Agricultural Library be given adequate resources to assume the consumer information and public education roles that the Office of Agricultural Biotechnology had initiated; (2) that an individual in your Office serve as the policy representative for biotechnology to the Committees and Sub-Committees of the National Science and Technology Council; and (3) that REE continue to support initiatives that advance the international trade of genetically engineered agricultural products. In regards to the last recommendation, I am hopeful that I can contribute to the resolution of the trade issues in another capacity. It has been my pleasure to have had the opportunity of serving REE, this Department and American Agriculture.

Cordially,

Alvin L. Young
Science Advisor and Scientific Director

Enclosure

cc: Dr. Bob Robinson, Administrator, CSREES
Dr. George Cooper, CSREES, Partnerships

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FINAL REPORT OF THE OFFICE OF AGRICULTURAL BIOTECHNOLOGY

SUMMARY

The USDA Office of Agricultural Biotechnology (OAB) was established by Secretary's Memorandum 1020-27, July 14, 1986 with "primary responsibility for implementing and coordinating the Department's policies and procedures pertaining to all facets of agricultural biotechnology". The OAB, at various times, reported to the Deputy Secretary, the Assistant Secretary for Science and Education, and the Under Secretary for Research, Education, and Economics. OAB had a small permanent staff and added detailees as necessary to address specific issues. Between 1987 and its closure in February 1996, the office utilized and supported mechanisms for biotechnology policy coordination, and provided a focus for research and biosafety advice, public outreach, and international coordination.

USDA Policy Coordination Mechanisms -- USDA instituted several mechanisms designed to coordinate activities, policies, and programs across USDA agencies involved in biotechnology. The Committee on Biotechnology in Agriculture (CBA), from 1986 to 1992, consisted of sub-cabinet officers and provided policy-level coordination for agricultural biotechnology. The Biotechnology Council, composed of senior-level staff, met monthly since 1992 and provided advice to the CBA and prepared USDA responses to issues which affected more than one agency.

Presidential Initiative on Biotechnology Research -- From 1991 to 1996, OAB served as the USDA action office in a U.S. Government-wide effort to track and analyze Federal investment and to identify research opportunities in biotechnology research. This effort involved the White House Office of Science and Technology Policy and a dozen Federal agencies with biotechnology research interests. Three reports were issued with the most recent one emphasizing research opportunities in agriculture, aquaculture, environment, and manufacturing/bioprocessing.

The Agricultural Biotechnology Research Advisory Committee -- The Agricultural Biotechnology Research Advisory Committee (ABRAC) was a Federal advisory committee, established by Departmental Regulation 1042-87, dated October 23, 1987. This committee was composed of 15 outside experts which advised USDA on the safe conduct of biotechnology research. ABRAC drafted guidelines for research involving planned introduction into the environment of genetically modified organisms and provided advice on a number of policy issues, including transgenic food animals, genetically modified *Rhizobia*, recombinant vaccines, and performance standards for research involving genetically modified fish and shellfish.

Public Outreach Activities--Biotechnology is of great interest to the agricultural research community, farm groups, teachers, students, businesses, and the average consumer. OAB sought to provide these groups and others with information about

biotechnology that was free of scientific or regulatory jargon. The information reflected both the potential advantages of this new science as well as its limitations. In addition to communicating the science, OAB strove to involve the public in the decision-making process by holding open-door advisory committee meetings around the country, sponsoring regional public information workshops, and by working cooperatively with other public affairs units in government and industry.

International Affairs -- The United States has enjoyed a competitive advantage in developing biotechnology products to help our farmers produce more efficiently and compete in international markets; however other nations are closing the gap. USDA, through the Office of Agricultural Biotechnology, has been involved in a number of international activities which have promoted U.S. competitiveness in agricultural biotechnology. These activities included science and technology, biosafety, and trade.

Administrative Actions and Expenditures of Resources (APPENDIX A) - Although the Office was established by Secretary's Memorandum in 1986, an Acting Director, Deputy Director and staff support were provided in 1987 and the first budget for the Office's operations was approved for FY 1989. Permanent Director, Dr. Alvin L. Young, and Deputy Director, Dr. Daniel D. Jones, were appointed by the Secretary of Agriculture in June 1989. At its peak of activity, the OAB had eight approved positions (5 professionals and 3 support) that provided a crosscut of USDA's biotechnology responsibilities (research, regulation, public outreach, and international). Twenty-two detailees from USDA Agencies served in the Office. At the time of its closing in February 1996 the Office had six permanent staff that were subsequently dispersed within the program areas of the Cooperative State Research, Education, and Extension Service (CSREES). The total estimated expenditure for the nine fiscal years from 1987 through 1995 was \$4.1 million. Approximately 71% of these funds were for staff salaries and benefits; 14% for equipment, supplies and other services; 8% for travel, and 7% for grants to support projects and symposia. From FY 1988 through FY 1995, 47 grants or agreements were provided to support 38 symposia, workshops or conferences, and 5 special projects. The 38 symposia, workshops or conferences sponsored or co-sponsored by the OAB encompassed the spectrum of interests in agricultural biotechnology by USDA. The OAB, in accordance with the Agency (CSREES) file plan for disposition of records, transferred or archived the Office and ABRAC records.

Presentations, Office Publications, Staff Professional Publications (APPENDIX B)- Communicating about agricultural biotechnology was a key responsibility of the Office of Agricultural Biotechnology. All of the professional staff were encouraged to accept speaking engagements, participate in workshops and conferences, and to publish in professional journals. The Office took the lead in developing publications for the public and in providing a newsletter for general distribution. From November 1987 through December 1995, a total number of 217 presentations were given to approximately

16,000 people. Fifty-four presentations were given locally (in Washington DC and the immediate area) to professional groups, agricultural commodity groups, public interest groups, high schools and colleges. Nationally, 128 presentations were given, while internationally 35 presentations were made. A list of special publications and proceedings prepared by the OAB, and professional publications are provided in APPENDIX B.

Current and Future Issues in Agricultural Biotechnology - In 1996, it is projected that more than 6 million acres in the United States will be growing genetically modified crops. It will be important for the Department of Agriculture to address issues of food safety, labeling, environmental safety, rural revitalization, intellectual property rights, and international trade.

OFFICE OF AGRICULTURAL BIOTECHNOLOGY

Authority, History, and Accomplishments

The USDA Office of Agricultural Biotechnology (OAB) was established by Secretary's Memorandum 1020-27 dated July 14, 1986. That Memorandum gave the Office "primary responsibility for implementing and coordinating the Department's policies and procedures pertaining to all facets of agricultural biotechnology." A second Secretary's Memorandum dated December 7, 1987, affirmed the coordinating role of OAB and transferred it to the Deputy Secretary. A third Secretary's Memorandum 9600-2, dated August 16, 1989, affirmed the coordinating role of OAB and transferred it to the Assistant Secretary for Science and Education.

In 1987, USDA formed an internal Biotechnology Management Working Group composed of representatives of APHIS, ARS, CSRS, ERS, FS, FSIS, and OAB and chaired by Dr. Marvin Norcross of FSIS. The charge to the Working Group was to develop recommendations concerning the adequacy of management and communications processes regarding plant pest, animal biologic, and research guidelines issues. After several months of interviews and discussion, the principal recommendations of the Working Group were the immediate appointment of a full-time Director of OAB with adequate professional and support staff, the establishment of the Agricultural Biotechnology Research Advisory Committee (ABRAC), and the transfer of OAB to the Office of the Deputy Secretary. These recommendations were accomplished in the fall of 1987. A permanent Director and Deputy Director were appointed by the Secretary in June 1989.

OAB Accomplishments:

- o Serving as USDA's point of contact for biotechnology to the public, media, and the international community;
- o Under a Presidential Initiative, OAB was the USDA action office for a multi-year budget crosscut initiative on biotechnology research;
- o OAB provided an Executive Secretary and staffed a Federal advisory committee, the Agricultural Biotechnology Research Advisory Committee (ABRAC), that provided a public forum for issues in agricultural biotechnology;
- o OAB provided an Executive Secretary and staffed the Committee on Biotechnology in Agriculture (CBA) composed of Administrators and Assistant Secretaries, and the Biotechnology Council composed of senior agency staff;
- o OAB provided leadership for the development of:
 - the Biotechnology Management Agenda, a quarterly summary of biotechnology goals, milestones, and progress;
 - biotechnology guidelines for agricultural research;
 - scientific exchanges involving biotechnology;
 - environmental assessments for transgenic fish;
 - advice when requested by regulatory agencies;
 - a biotechnology consumer information plan for USDA.
- o The Director of OAB served as USDA's representative to the Biotechnology Research Subcommittee, Committee on Fundamental Science, National Science and Technology Council; to the United States -European Union Task Force on Biotechnology Research; and as the research agencies' representative to the Department of State's Coordinating Committee on Biotechnology.

POLICY COORDINATION OF BIOTECHNOLOGY AT USDA

The Department of Agriculture established several internal mechanisms for addressing and resolving biotechnology issues that cut across agency lines.

Committee on Biotechnology in Agriculture

In 1986, the Department established a policy-level Committee on Biotechnology in Agriculture (CBA) composed of the administrators of six USDA agencies with significant biotechnology programs. The CBA was co-chaired by the Assistant Secretary for

Science and Education and the Assistant Secretary for Marketing and Inspection Services, and the Director of OAB was the Executive Secretary.

USDA's Biotechnology Council

A subcommittee of the CBA, called the Biotechnology Council, was composed of eleven senior staff from seven USDA agencies. The Council, which met monthly, provided a forum for the discussion of policy issues and the development of recommendations for the co-chairs of the CBA. The membership current at the time of OAB closure is provided in APPENDIX C. Accomplishments of the Council included:

- o Developed USDA comments on EPA's proposal on the use of the Federal Insecticide, Fungicide and Rodenticide Act and the Federal Food, Drug and Cosmetic Act in regulating plants containing pesticidal substances;
- o Prepared comments on the Food and Drug Administration's clarification of food safety policy on foods from new plant varieties;
- o Developed Departmental response to EPA's proposed rule on small-scale testing of microbial pesticides;
- o Reviewed the Animal and Plant Health Inspection Service's proposed rule to streamline approval of field testing under the Federal Plant Pest Act by establishing a notification system (in lieu of requiring permits) for certain tests conducted according to a set of standards, and to establish a system for exemption from regulation under the Federal Plant Pest Act;
- o Reviewed a clarification of policy developed by the Food Safety and Inspection Service, to explain how existing inspection regulations covering experimental animals will be used in the pre-marketing food safety review and approval of transgenic livestock and poultry;
- o Provided comments during the drafting stage of the 1992 National Biotechnology Board's report. The Assistant Secretary for Science and Education represented USDA on the Board.
- o Provided comments during the drafting stages of the three Biotechnology Reports of the Executive Office of the President, Biotechnology for the 21st Century (February 1992), Biotechnology for the 21st Century: Realizing the Promise (June 1993), and Biotechnology for the 21st Century: New Horizons (July 1995).

PRESIDENTIAL INITIATIVE ON BIOTECHNOLOGY RESEARCH

On January 31, 1992, the Executive Office of the President announced a Presidential Initiative on Biotechnology Research. This was one of several budget initiatives on science and technology issues that cut across Federal agencies. Other budget crosscuts included global warming, high-performance computing, mathematics and science education, and new materials and manufacturing.

The biotechnology crosscut initiative recognized the critical role of biotechnology in future technological strength, economic growth, and the health and quality of life for the United States. It was an integral component of the President's overall approach to challenges in science, technology, and education. Improvements in the scientific and engineering research base in biotechnology will have far-reaching effects and will lead to important enhancements in the quality of life of our citizens as well as in manufacturing, agriculture and aquaculture, mineral processing, and the production of chemicals and fuels.

Twelve Federal agencies participated in the biotechnology crosscut. Their efforts on the biotechnology crosscut were coordinated by the Biotechnology Research Subcommittee (BRS) of the Committee on Fundamental Science of the National Science and Technology Council, Executive Office of the President.

OAB and The Biotechnology Crosscut

From 1992 to 1996, OAB was the USDA action office for the biotechnology crosscut. OAB collected research program and budget data from the Agricultural Research Service, Cooperative State Research Service, Economic Research Service, and Forest Service, assembled it into a consistent format and submitted it to the BRS. OAB also chaired the BRS Agriculture Working Group that coordinated the collection of information on biotechnology research program components and identified research opportunities in cooperation with 8 non-USDA agencies with research programs related to agriculture.

The biotechnology crosscut featured different areas of research in successive years. In FY 1994 it was health and environment; for FY 1996 it was agriculture, environment, aquaculture, and manufacturing/bioprocessing. OAB coordinated and assembled the agricultural portion of the report for the entire Federal government.

AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE

The USDA Agricultural Biotechnology Research Advisory Committee (ABRAC) was established by Departmental Regulation 1042-87, dated October 23, 1987 and rechartered three times thereafter. The purpose of ABRAC was to provide advice to the Secretary through the Under Secretary for Research, Education and Economics on policies, programs, operations, and activities associated with the conduct of agricultural biotechnology research. The ABRAC was also cited for consultation by the Secretary in the 1990 Farm Bill, Section 1668, Biotechnology Risk Assessment Research.

The ABRAC consisted of 15 doctoral-level experts with knowledge in one or more of the following areas: recombinant-DNA research in plants, animals, and microbes; food science; ecology/epidemiology/environmental science; agricultural production practices; biological containment and biological field release; applicable laws and regulations; standards of professional conduct and practice; public attitudes; public health; occupational health and ethics; human medicine; fisheries science; and socioeconomic impacts. The Office of Agricultural Biotechnology provided executive secretarial and staff support for the ABRAC. The membership of ABRAC by two-year increments (period of appointment) from 1988 through closure in 1996 is provided in APPENDIX C.

The first major accomplishment of the ABRAC was a set of *Guidelines for Research Involving Planned Introduction into the Environment of Genetically Modified Organisms*. These guidelines were modeled in part after a 1989 report of the Ecological Society of America and tailored by the ABRAC to the needs of the agricultural research community. They were published in the *Federal Register* for public comment, submitted as a recommendation to the Department in March, 1992, and distributed as voluntary guidelines to State Agricultural Experiment Stations and other interested parties.

The ABRAC also reviewed and developed recommendations on individual research proposals. The most notable and highly publicized were proposals for studies of transgenic fish in outdoor research ponds at Auburn University. Based on ABRAC recommendations, CSRS prepared appropriate environmental documentation and approved studies for transgenic carp in 1990 and transgenic catfish in 1992.

In order to reduce the need for resource-intensive case-by-case evaluations in the future, ABRAC took the lead in developing more generic performance standards for confinement of genetically modified aquatic organisms in outdoor facilities. The ABRAC drafted *Performance Standards for Safely Conducting Research with Genetically Modified Fish and Shellfish* with wide participation and support from the

aquatic research community, industry, regulators, and environmental interest groups. The ABRAC finalized the aquatic performance standards and transmitted them to the Under Secretary for Research, Education and Economics on August 2, 1995. In response to ABRAC recommendations, the Performance Standards were converted to electronic format for ease of use by researchers and others. The Department also funded a proposal to hold Federal/State workshops to introduce the performance standards to the research community, natural resource officials, and State and regional regulators. This task was to be done by the National Biological Impact Assessment Program, Virginia Polytechnic Institute and State University. At its final meeting, January 19, 1996, ABRAC reviewed the status and accomplishments of the Department's Biotechnology Risk Assessment Research Program. The ABRAC recommended that the Department continue supporting this program. The ABRAC also reviewed proposed educational initiatives.

USDA regulatory agencies requested ABRAC review of selected biotechnology activities. In 1992, an ABRAC Risk Assessment Working Group reviewed the scientific aspects of the recent field testing notification proposal of APHIS. On April 8, 1993, an ABRAC Transgenic Animal Working Group, at the request of FSIS, reviewed the proposed policies and procedures for the inspection of transgenic animals presented for slaughter in USDA-inspected establishments. It completed final recommendations on these policies at its meeting of June 29-30, 1993 and submitted them to the Department. FSIS adopted these recommendations with minor changes in a *Federal Register* notice of March 17, 1994.

ABRAC also addressed food safety issues raised by the use of genetically modified organisms in agricultural research and production through the sponsorship of a workshop on societal issues in food biotechnology, organized by the North Carolina Biotechnology Center in Research Triangle Park, North Carolina, June 30-July 1, 1993. Proceedings of that workshop were published.

The ABRAC also participated in a series of international biosafety symposia that addressed biosafety issues such as:

- Are field testing risks scale-dependent?
- Can small-scale results be extrapolated to larger scale?
- What are the long-term effects, if any, of agricultural field testing?
- Are there unique risks when testing genetically modified organisms in natural centers of diversity?
- Are there unresolved issues regarding the possible generation of new viral pathogens from transgenic plants?
- Do transgenic animals expressing human proteins for pharmaceutical use pose unique risks or other problems when presented for entry into the human food chain?

- Does classical toxicology offer a useful perspective in assessing the safety of food products produced by biotechnology?

PUBLIC OUTREACH ACTIVITIES

Over the last 8 years, OAB has employed various information vehicles to reach as wide an audience as possible, including: media interviews, conferences, exhibits, and publications. Specific examples are outlined below:

Examples:

A. Media Interviews

1. Print media: Total interviews: 100-200

(*New York Times, LA Times, San Francisco Examiner, USA Today, The Washington Post, the Washington Times, Bureau of National Affairs, Farm Journal, Sacramento Bee, Family Circle Magazine, Progressive Farmer, Food Chemical News, Chemical and Engineering News, Diversity Magazine, Forbes, Christian Science Monitor, Kansas City Star, Chicago Tribune, DVM News Magazine, Daily Pennsylvanian, Nature, Biotech Newswatch, Science, The Scientist, Washington Aqua Farm Letter, Farm Forum, AgBiotech News, Wisconsin BioIssues, Genetic Engineering News, Bio/Technology, Monitor*)

2. Wire and news services: Total interviews: 75-100

3. Radio and TV interviews: Total: 50-75

B. Conferences and exhibits

1. "Biotechnology and the Public": 1988, 4 regional meetings
2. "Methods of Communicating Biotechnology With the Public": 1993, joint USDA-EC conference
3. "Biotechnica Hannover": 1992, Hannover, Germany; USDA exhibit
4. Exhibited at "New Strategies for Reaching the Global Consumer," November 1995, Washington, DC

C. Publications

1. "Biotechnology Notes": Free, monthly, no-frills, 8-page newsletter that covers USDA's biotech research, regulations, and policies. Published from May 1988 to February 1996. Total issues: 80; Distribution: 500,000, mostly via electronic means.
2. "The ABC's of Biotechnology": Fact sheet for consumers; 1989
3. "Biotechnology at USDA": Brochure highlighting biotech programs and points of contact at each USDA agency; 1992
4. "Public Relations: The Scientist and the Public, the Government, and the Media," in "Agricultural Biotechnology: Handbook for Field Testing": October, 1989
5. Proceedings of conference entitled "Methods of Communicating Biotechnology with the Public": December 1992
6. "A Government Agency's Responsibility to the Consumer," in *Journal of Nutrition*. In press.
7. Reprints of biotechnology articles drawn from *Agricultural Research Magazine*. 1993, 1994, and 1995. Total copies distributed: 15,000

INTERNATIONAL ISSUES IN AGRICULTURAL BIOTECHNOLOGY

As the first nation to widely apply the tools of modern biotechnology to agriculture, the United States enjoys a competitive advantage in developing biotechnology products to help U.S. farmers produce more efficiently and compete in international markets. Despite this lead, others nations are also investing in this technology, and the gap between the United States and European nations, Japan, China, and other countries may be closing.

There are a number of issue areas within the purview of the U.S. Department of Agriculture which will help determine the impact of agricultural biotechnology on U.S. competitiveness in agriculture. These include the size and effectiveness of our investment in basic and applied research, the success of our efforts in stimulating the commercialization of discoveries (technology transfer), the effectiveness of our regulatory programs, and our ability to have the products of agricultural biotechnology accepted by our trading partners.

OAB Accomplishments:

Science and Technology -- In order to monitor the relative effectiveness of our investment in agricultural biotechnology, the Office of Agricultural Biotechnology, in cooperation with the Agricultural Research Service, and the Foreign Agriculture Service's International Cooperation and Development (ICD) unit, conducted a study of research and technology transfer programs in competing nations. These studies also involved identifying opportunities for collaboration where the United States stood to gain important scientific or technical knowledge from other nations. Examples of these activities included: the U.S. - European Community Task Force on Biotechnology Research; technology assessment visits to Japan and China; and the U.S. - Ireland Workshop on Applications of Biotechnology to Fish Diseases.

Biosafety -- Another important international activity of OAB was promoting international consensus on the scientific principles which underpin the environmental and human safety of agricultural biotechnology. Reaching a consensus is imperative if other nations are to accept our agricultural biotechnology products and the food and fiber we produce with these products. A key forum for these discussions was the Organization for Economic Cooperation and Development Group of National Experts on Safety in Biotechnology.

Other activities included USDA sponsorship of three biennial International Symposia on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms, and many bilateral consultations between the Animal and Plant Health Inspection Service (APHIS) and their counterparts abroad. OAB worked with the Food Safety and Inspection Service, APHIS, ARS, the former Cooperative State Research Service (CSRS) and ICD to sponsor an international workshop on animal biotechnology safety and related issues in April 1994 in Davis, California. Scientists and policy makers from 14 nations participated.

Trade -- As the products of biotechnology enter the international marketplace, special efforts may be necessary to explain the procedures the United States has used to ensure their safety. For example, OAB worked extensively with the U.S. Trade Representative, the Food and Drug Administration and the Foreign Agricultural Service to provide information to our trading partners on the scientific criteria being used in the review of bovine somatotropin. In order to reach a larger audience with information on the variety of agricultural biotechnology products expected to be traded during the next five years, OAB also organized a one-day program on agricultural biotechnology for foreign diplomats at the National Arboretum.

CURRENT AND FUTURE ISSUES IN AGRICULTURAL BIOTECHNOLOGY

Food Safety and Biotechnology -- The tools of biotechnology may be useful in preventing and detecting food safety problems. At the same time consumers have indicated they have concerns about the safety of using biotechnology to create new food products.

Labeling of Biotechnology Foods -- Food and Drug Administration (FDA) policy does not currently require labeling of foods produced with biotechnology unless there is a significant change in nutrient, toxin, or allergen content. Yet consumers have expressed a preference for labeling. Labeling raises a number of complex legal, economic, and enforcement issues.

Rural Revitalization and Biotechnology -- Biotechnology is one of the critical technologies which the President and Vice President have identified in a publication entitled "Technology for America's Economic Growth, A New Direction to Build Economic Strength." Agricultural biotechnology offers the possibility of creating jobs and revitalizing rural areas while helping U.S. farmers to become more competitive. Yet some small producers fear that biotechnology may put them at a competitive disadvantage. Huge impacts upon American agriculture will likely occur because of biotechnology. USDA needs to plan how to manage this expected change in the structure of production agriculture.

Environmental Safety and Biotechnology -- Biotechnology may prove an extremely important tool in mitigating the negative impacts of agriculture on the environment. USDA has in place effective regulatory and research programs aimed at ensuring that biotechnology is developed safely. However, environmental groups continue to voice concerns that introductions of genetically modified organisms may inadvertently harm the environment.

Biotechnology and Aquaculture -- The further development of aquaculture will depend on solving many of the technical and environmental issues facing the industry. Biotechnology research can be helpful in addressing these issues.

Intellectual Property Rights (IPR) -- There is a general consensus among the biotechnology research community that adequate protection of intellectual property is basic to the successful development of biotechnology products. Yet areas of disagreement persist, nationally and internationally, about various aspects of IPR including patenting life, a farmers exemption, a research exemption, scope of patents, patent harmonization and biodiversity and patenting.

APPENDIX A

ADMINISTRATIVE ACTIONS AND EXPENDITURES OF RESOURCES

APPENDIX A

ADMINISTRATIVE ACTIONS AND EXPENDITURES OF RESOURCES

Personnel

Table A-1 lists the personnel who have staffed the Office of Agricultural Biotechnology between the period November 1987 to February 1996. The Cooperative State Research Service, subsequently the Cooperative State Research Education and Extension Service, CSREES, provided the support for the office. Hence, permanent staff were assigned to and on the roster of CSREES. Note also that three university individuals participated under Interagency Personnel Agreements with the Office, and that detailees came to the Office from all of the USDA agencies having programmatic responsibilities for biotechnology. The concept of having detailees worked very well for the OAB. It allowed the Director to access area specialists (e.g., economics or international affairs) while at the same time providing a Departmental level crosscut exposure for those individuals on details.

Budget

The total estimated expenditure for the nine fiscal years from 1987 through 1995 was \$4.1 million (see Table A-2). Approximately 71% of these funds were for staff salaries and benefits; 14% for equipment, supplies and other services; 8% for travel; and 7% for grants to support projects and symposia. Generally, the costs of salaries for detailees were graciously provided by the contributing agencies and those figures are not reflected in the OAB budgets.

Symposia and Special Projects

Table A-3 provides an overview of the grants and agreements negotiated in support of special projects or symposia, workshops or conferences. From FY 1988 through FY 1995, 47 grants or agreements were provided to support 38 symposia, workshops or conferences, and 5 special projects. The special projects included the development of a computerized database system with the University of Minnesota for \$30,000. This system subsequently became the forerunner of the National Biological Impact Assessment Program. The University of Florida received 3 Cooperative Agreements totaling \$53,000 for preparing the first draft of research guidelines. These guidelines became the Working Document for the Agricultural Biotechnology Research Advisory Committee's (ABRAC) successful efforts to develop GUIDELINES FOR RESEARCH INVOLVING PLANNED INTRODUCTION IN THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS, published on December 1991. A \$96,000 agreement with Purdue University resulted in the publication AGRICULTURAL BIOTECHNOLOGY: ISSUES AND CHOICES, 1991, B.R. Baumgardt and M.A. Martin, co-editors. Similarly, a project with Mississippi State University resulted in the publication AGRICULTURAL BIOTECHNOLOGY: INTRODUCTION TO FIELD TESTING, 1990, H.G. Purchase and D.R. Mackenzie, co-editors.

The 38 symposia, workshops or conferences sponsored or co-sponsored by the OAB encompassed the spectrum of interests in agricultural biotechnology by USDA. Table A-4 provides a summary of the sponsored activities. The budget data from Table A-2 reported that the OAB committed approximately \$276,000 to grants and agreements to fund special projects and symposia. However, Table A-3 reported that the total for these grants and agreements was approximately \$613,000. The difference reflects the funding provided by other agencies as co-sponsors of symposia. The total cost of the special projects was about \$225,000, therefore OAB provided \$51,000 to sponsor symposia while other agencies contributed approximately \$337,000. This leveraging of funds (\$1 OAB: \$6.5 other agencies) reflected the philosophy of the Office, namely, that the OAB identified topic areas for support and provided the "seed" funds to plan, organize and hold the numerous symposia. This activity will be more difficult for USDA to manage with the closing of the Office.

Disposition of Records

The OAB, in accordance with the Agency file plan for disposition of records, transferred selected files and records to other offices of primary interest. Records of the Committee on Biotechnology in Agriculture and the Biotechnology Council were sent to the current Chair of the Biotechnology Council, Dr. Richard Parry, ARS. The chronological file of the OAB for the past year was sent to the Acting Deputy Administrator, CSREES/Partnerships, Dr. George Cooper. Records of the Agricultural Biotechnology Research Advisory Committee were sent to the Washington National Records Center. Extra copies of biotechnology publications were sent to Dr. Ray Dobert, Biotechnology Information Center, National Agricultural Library, Beltsville, MD.

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF AGRICULTURAL BIOTECHNOLOGY

TABLE A-1 - Source Agencies for Staff and Detailees, November 1987 - February 1996

Cooperative State Reserch Education and
Extension Service

Angela Beale
Elsie Brown
Tim Grosser
Matilda Merritt
Eva Russnak
Barry Stone
Gary Weber
Alvin Young

Office of Public Affairs
Marcella Hilt

State Agricultural Experiment Stations

John Gerber
Michael Olexa
Paul Stern

Agricultural Research Service

Philip O'Berry
Charles Lewis
Marshall Phillips
Graham Purchase

Food Safety and Inspection Service

Maryln Cordle
Daniel Jones
Jim Rasekh

Forest Service

Milton Robinson
Lambert Wenner

Animal and Plant Health Inspection Service

Marti Asner
Althaea Langston

Economic Research Service

Fred Kuchler

National Agricultural Library

Jean Larson

International Cooperation and Developement

Martha Steinbock

TABLE A-2
OFFICE OF AGRICULTURAL BIOTECHNOLOGY
ESTIMATED EXPENDITURES/OPERATING BUDGETS
FY 1987-1995

FY	OC2100 TRAVEL	OC2200 TRANS OF THINGS	OC2300 RENT COMM., UTIL	OC2400 PRINTING	OC2500 OTHER SERVICES	OC2600 SUPPLIES	OC3100 EQUIPMENT	SUBTOTAL	OC4000 GRANTS/ AGREEMENTS-	SALARY/ FRINGE BEN.	GRAND TOTAL
1987	\$15,200.00	\$3,000.00	\$0.00	\$0.00	\$18,500.00	\$7,000.00	\$23,500.00	\$67,200.00	\$30,000.00	\$107,550.00	\$204,750.00
1988	\$15,200.00	\$0.00	\$0.00	\$0.00	\$84,613.00	\$8,000.00	\$22,725.00	\$130,538.00	\$65,000.00	\$111,227.00	\$306,765.00
1989	\$19,000.00	\$0.00	\$0.00	\$0.00	\$91,500.00	\$9,625.00	\$8,800.00	\$128,925.00	\$20,700.00	\$187,168.00	\$336,793.00
1990	\$43,000.00	\$0.00	\$0.00	\$0.00	\$97,884.00	\$4,125.00	\$7,000.00	\$152,009.00	\$40,000.00	\$276,991.00	\$469,000.00
1991	\$60,496.00	\$100.00	\$7,500.00	\$0.00	\$23,353.00	\$13,100.00	\$13,400.00	\$117,949.00	\$25,000.00	\$372,591.00	\$515,540.00
1992	\$65,000.00	\$0.00	\$4,000.00	\$0.00	\$28,449.00	\$10,000.00	\$10,500.00	\$117,949.00	\$25,000.00	\$479,402.00	\$622,351.00 ¹
1993	\$34,889.00	\$250.00	\$200.00	\$0.00	\$25,000.00	\$3,000.00	\$4,000.00	\$67,339.00	\$20,292.00	\$533,632.00	\$621,263.00
1994	\$30,634.00	\$200.00	\$0.00	\$0.00	\$16,000.00	\$2,000.00	\$11,300.00	\$60,134.00	\$20,970.00	\$496,181.00	\$577,285.00
1995	\$22,306.00	\$10.00	\$602.00	\$0.00	\$7,586.00	\$1,851.00	\$9,568.00	\$41,923.00	\$29,000.00	\$384,720.00	\$455,643.00 ²
TOTAL	\$305,725.00	\$3,560.00	\$12,302.00	\$0.00	\$392,885.00	\$58,701.00	\$110,793.00	\$41,923.00	\$275,962.00	\$2,949,462.00	\$4,109,390.00

February 1, 1995

¹Total does not include \$35,800 reimbursable funds from other agencies to support Dublin Workshop.

²Due to reorganization, OAB was subsumed into CSREES Partnerships Unit and did not have an official operating budget for FY 1995. Therefore, figures shown for FY 1995 are estimates.

TABLE A-3

CONFERENCES AND PROJECTS SPONSORED
OR CO-SPONSORED
BY THE
OFFICE OF AGRICULTURAL BIOTECHNOLOGY
(FY 1988-1995)

(COOPERATIVE AGREEMENTS/GRANTS/REIMBURSABLE AGREEMENTS)

Prepared : January 30, 1996

FY	AGREEMENT #	RECIPIENT	LOCATION	DESCRIPTION	DURATION	AMOUNT	DATES
1988	88-COOP-1-4052	INSTIT. OF FOOD & AGR'L SCIENCES-U. OF FL	FL	THE DEVELOPMENT OF DRAFT BIOTECHNOLOGY GUIDELINES & RELATED MATERIALS	9/2/88-2/4/89	\$23,000.00	
1988	88-COOP-1-3247	UNIV. OF MINNESOTA	MN	AGRICULTURAL BIOTECHNOLOGY REGISTRY & DATABASE MANAGEMENT SYSTEM	7/15/86-12/31/88	\$30,000.00	
1988	88-COOP-1-4052.1	UNIV. OF FLORIDA	FL	THE DEVELOPMENT OF DRAFT BIOTECHNOLOGY GUIDELINES & RELATED MATERIALS, AMEND. 1		\$12,200.00	
1988	88-COOP-1-4181	PURDUE UNIVERSITY	IN	SOCIO-ECONOMIC IMPACTS OF BIOTECHNOLOGY FORUM ON VETERINARY PERSPECTIVES ON GENETICALLY ENGINEERED ANIMALS	9/1/88-3/31/92	\$86,000.00	
1988	88-COOP-2-4154	AMERICAN VETERINARY MEDICAL ASSOC. (AVMA)			9/12/88-3/11/89	\$2,500.00	9/19-20/88
1989	CSRS-928-0525-1	EXTENSION SERVICE	DC	VIDEO TELECONFERENCE ON BIOTECHNOLOGY SYMPOSIUM ON BIOTECHNOLOGY	10/1/88-9/30/89	\$12,000.00	11/4/88
1989	89-COOP-2-4213	ALABAMA A&M UNIVERSITY	AL	A WORKSHOP-INTERACTION OF UV-B AND CROP PLANTS	11/7/88-11/6/89	\$2,500.00	
1989	89-COOP-2-4266	UNIV. OF FLORIDA	FL		2/11/89-6/30/89	\$35,000.00	2/13-15/89
1989	89-COOP-2-4212	TEXAS A&M UNIVERSITY	TX	BIOTECHNOLOGY IN OUR FUTURE--THE CHALLENGE TO APPLY IT	11/1/88-4/30/89	\$1,240.00	11/11/88
1989	89-COOP-1-4385	UNIV. OF FLORIDA	FL	PROGRAM FOR IMPLEMENTATION OF RESEARCH GUIDELINES AND RELATED MATERIALS FOR ABRAC	4/3/89-9/30/89	\$17,868.00	
1989	89-COOP-2-4265	PUBLIC VOICE	DC	BIOTECHNOLOGY AND THE FOOD SUPPLY--LOOKING AT THE TOUGH ISSUES	3/1/89-9/1/89	\$15,000.00	3/22-23/89
1989	89-COOP-2-4217	UNIVERSITY OF MAINE	ME	FIRST INTERNATIONAL SYMPOSIUM ON THE MOLECULAR BIOLOGY OF THE POTATO	1/1/89-12/31/89	\$2,500.00	8/13-18/89
1989	89-COOP-2-4211	AMERICAN PHYTOPATHOLOGICAL SOCIETY (APS)	MN	APS COLLOQUIUM: RISK ASSESSMENT FOR THE UTILIZATION OF MICROORGANISMS IN THE ENV.	11/1/88-3/31/89	\$2,500.00	11/15/88
1990	90-COOP-2-4977	AMERICAN SOCIETY OF AGRONOMY (ASA)		FIELD TESTING OF GENETICALLY MODIFIED ORGANISMS	12/13/89-4/30/90	\$6,000.00	12/11-15/89
1990	90-COOP-2-4970	BIOTECHNOLOGY INSTITUTE FOR TECHNOLOGY TRANSFER	FL	2ND INTERNATIONAL BIOTECHNOLOGY SYMPOSIUM	11/15/89-1/31/90	\$5,000.00	
1990	03T590-60-3204-0-10	ARS	DC	EVALUATION STUDIES-ENVIRONMENTAL IMPACT STATEMENT PROCESS		\$38,858.00	
1990	90-COOP-2-5013	UNIV. OF ILLINOIS	IL	MAPPING DOMESTIC ANIMAL GENOMES: NEEDS & OPPORTUNITIES CONFERENCE	3/1/90-2/28/91	\$15,000.00	4/8-10/90
1990	CSRS-028-0525-5	FOREST SERVICE	DC	INTERNAT'L SYMP. ON APPLICATION & UTIL. CHNOLOGY TO TREE CULTURE, PROTECTION	9/6/90-9/30/90	\$4,000.00	8/5-8/91
1990	90-COOP-2-5145	UNIV. OF MARYLAND	MD	THIRD INTERNATIONAL SYMPOSIUM ON AGRICULTURAL BIOTECHNOLOGY	7/1/90-12/31/90	\$5,000.00	9/24-26/90
1990	90-COOP-2-5213	PUBLIC VOICE	DC	BIOTECHNOLOGY & THE FOOD SUPPLY--AN INTERNATIONAL CONF. IN BRUSSELS	5/31/90-10/30/90	\$19,200.00	5/31-6/1/90
1991	91-COOP-2-5918	AMERICAN INSTIT. OF BIOL. SCIENCES (AIBS)	DC	INTERNATIONAL CONFERENCE ON THE OPTIMIZATION OF PLANT PRODUCTIVITY	3/1/91-8/31/91	\$18,000.00	3/7-9/91
1991	CSRS-228-0525-2	DEPARTMENT OF COMMERCE	DC	BIOTECHNICA HANNOVER '91 INTERNATIONAL CONGRESS & EXHIBIT	10/8/91-9/30/92	\$5,600.00	10/22-24/91
1991	CSRS-128-0525-1	FOREST SERVICE	DC	APPLICATIONS OF BIOTECHNOLOGY TO TREE CULTURE, PROTECTION & UTILIZATION	1/25/91-9/30/91	\$11,000.00	8/5-8/91
1991	88-COOP-1-4181.2.3	PURDUE UNIVERSITY	IN	SOCIO-ECONOMIC IMPACTS ON BIOTECHNOLOGY (AMEND. #2 (NO COST) & #3	9/1/88-3/31/92	\$10,000.00	
1991	CSRS-128-0101-3	EXTENSION SERVICE	DC	BIOTECH FOR CONTROL OF GROWTH & PRODUCT QUALITY IN MEAT PROD.-IMP. & ACCEPT.		\$6,000.00	

FY	AGREEMENT #	RECIPIENT	LOCATION	DESCRIPTION	DURATION	AMOUNT	DATES
1991	91-COOP-2-5825	CLEMSON UNIVERSITY	SC	INTERNAT'L SYMP. ON THE BIOSAFETY RESULTS OF FIELD TESTS OF GENETICALLY MODIFIED	11/27/90-5/27/91	\$20,000.00	11/27-30/90
1992	FSIS-12-37-2-0066	IA STATE UNIVERSITY	IA	ANIMAL BIOTECH.: TECHNOL. TRANSFER & INDUSTRIAL NEEDS (NCR-150)	5/13/92-9/30/92	\$5,400.00	5/17-19/92
1992	92-COOP-2-6913	ISIS	DC	REGIONAL ROUNDTABLE ON PLANT BIOTECHNOLOGY	12/1/91-2/24/92	\$2,000.00	12/11/91
1992	92-COOP-2-7379	PUBLIC VOICE	DC	BIOTECHNOLOGY & THE FOOD SUPPLY WORKSHOP: CONSUMER INFORMATION IN THE NEW MARKETPLACE	5/1/92-9/30/92	\$10,000.00	7/13/92
1992	92-COOP-2-7164	CLEMSON UNIVERSITY	SC	INTERNAT'L SYMP. ON THE BIOSAFETY RESULTS OF FIELD TESTS OF GENETICALLY MODIFIED PLANTS & MICROORGANISMS	4/1/92-12/31/92	\$10,000.00	11/27-30/90
1992	92-COOP-2-7272	TISSUE CULTURE ASSOCIATION, INC.	DC	WORLD CONGRESS ON CELL AND TISSUE CULTURE	6/1/92-8/31/92	\$4,000.00	6/20-25/92
1992	92-COOP-2-6911	UNIV. OF CALIFORNIA-DAVIS	CA	MOLECULAR CROP AGRICULTURE FOR THE PACIFIC RIM CONFERENCE, JUNE 20-24, 1992	12/1/91-9/30/92	\$5,000.00	6/20-24/92
1992	90-CSA-GA1-113	UNIV. OF GEORGIA	GA	FOOD BIOTECHNOLOGY SESSION OF IBEX '91	10/1/91-11/31/91	\$1,000.00	
1992	92-COOP-2-8323	NC BIOTECHNOLOGY CENTER	NC	RESPONDING TO SOCIETAL ISSUES OF FOOD BIOTECHNOLOGY (ABRAC FUNDS)	8/1/92-5/31/93	\$42,000.00	
1993	93-COOP-2-8345	INSTITUTE FOR SCIENCE IN SOCIETY (ISIS)		BIOTECHNOLOGY CONFERENCE	11/1/92-7/15/93	\$10,000.00	6/10-11/93
1993	NO FUNDS AVAILABLE	ARS		AN INTERNATIONAL SYMPOSIUM ON RICE BLAST DISEASE		\$0.00	
1993	93-COOP-2-9555	MICHIGAN STATE UNIV.	MI	IDENTIFICATION OF NAT'L NEEDS FOR COLLABORATION BETWEEN 1862 & 1890 LAND-GRANT UNIVERSITIES IN AG BIOTECH	9/1/93-8/31/94	\$5,000.00	2/14/94
1993	92-COOP-2-8434	ALABAMA A&M	AL	BIOTECHNOLOGY APPLICATIONS IN DEVELOPING COUNTRIES	7/1/93-10/31/93	\$2,500.00	7/10-14/93
1993	93-COOP-2-8427	UNIV. OF MAINE	ME	THIRD INTERNATIONAL SYMPOSIUM ON THE MOLECULAR BIOLOGY OF THE POTATO	3/1/93-12/31/93	\$4,000.00	7/25-30/93
1994	94-COOP-2-1274	UNIVERSITY OF CALIFORNIA-DAVIS	CA	3rd INTERNAT'L SYMP. ON BIOSAFETY RESULTS OF FIELD TESTS OF GENETICALLY MOD. PLANTS & MICROORGANISMS	9/1/94-8/31/95	\$29,800.00	11/13-16/94
1994	94-COOP-2-0003	UNIV. OF CONNECTICUT	CT	3rd ANNUAL NEW ENGLAND REGIONAL ANIMAL BIOTECHNOLOGY SYMPOSIUM	12/1/93-6/30/94	\$3,420.00	4/20-21//94
1994	CSRS-428-0525-1	IOWA STATE UNIV.	IA	FUTURE GENETICS FOR THE ANIMAL INDUSTRY (NCR-150)	1/31/94-4/30/94	\$3,790.00	
1994	94-COOP-2-0098	UNIVERSITY OF CALIFORNIA - DAVIS	CA	INTERNATIONAL WORKSHOP ON ANIMAL BIOTECHNOLOGY ISSUES	4/1/94-9/30/94	\$21,047.00	4/6-9/94
1994	CSRS-428-0525-5	FOREST SERVICE	DC	2nd INTERNATIONAL SYMPOSIUM ON APPLICATIONS OF BIOTECH. TO TREE CULTURE, PROTECTION & UTILIZATION	9/9/94-9/30/94	\$2,500.00	10/2-6/94
1995	95-COOP-2-2536	GEORGETOWN UNIVERSITY	DC	INTERNATIONAL SYMPOSIUM ON BIOTECHNOLOGY AND SOCIETY	9/1/95-8/31/96	\$19,185.00	
1995	95-COOP-2-2553	VPI & STATE UNIVERSITY	VA	COMPUTERIZATION OF FISH/SHELLFISH PERFORMANCE STANDARDS (ABRAC FUNDS)	9/1/95-8/31/96	\$9,707.00	
1995	95-COOP-2-2413	NATIONAL FFA FOUNDATION	WI	AGRICULTURAL BIOTECHNOLOGY EDUCATION CAPACITY DEVELOPMENT	9/1/95-8/31/96	\$7,500.00	11/10/95
1995	95-COOP-2-1333	GEORGETOWN UNIVERSITY	DC	PLANNING AAAS & FASEB AGRICULTURAL BIOTECHNOLOGY COMMUNICATION SYMPOSIA	2/1/95-1/31/96	\$9,000.00	2/16-21&4/9-13
GRAND TOTAL						\$612,815.00	01/26/96

Table A-4: General Topic Areas and Numbers of Symposia, Workshops and Conferences
Sponsored or Co-Sponsored by the Office of Agricultural Biotechnology, FY 1988 - FY 1995.

<u>TOPIC AREA</u>	<u>NUMBER</u>
Animal Biotechnology	7
Plant/Crop Biotechnology	6
Consumer/Societal Issues of Food Biotechnology	5
Public Policy Issues	5
BioSafety of Field Testing	3
Forestry Biotechnology	3
Educational Initiatives	3
Extension and Biotechnology	2
Microbiology/Remediation	2
International (Biotechnology in Developing Countries)	2
	<hr/>
Total -	38

APPENDIX B

PRESENTATIONS, OFFICE PUBLICATIONS AND STAFF PROFESSIONAL PUBLICATIONS

APPENDIX B

PRESENTATIONS, OFFICE PUBLICATIONS, AND STAFF PROFESSIONAL PUBLICATIONS

Communicating about agricultural biotechnology was a key responsibility of the Office of Agricultural Biotechnology (OAB). All of the professional staff were encouraged to accept speaking engagements, participate in workshops and conferences, and to publish in professional journals. The Office took the lead in developing publications for the public and in providing a newsletter for general distribution.

Biotechnology Notes

After almost 8 years of publication and about 80 issues, USDA's chief source of news about agricultural biotechnology was *Biotechnology Notes*. The news publication began in May 1988 and broadened in scope over the years to include information about research, policy, technology transfer, regulations, communications, foreign affairs, and education. Thousands of people around the world either subscribed to the publication or received it via other communications channels. In 1989, its editor, Marti Asner, received a First Place Blue Pencil Award for *Biotechnology Notes* in the category "Periodical for Technical Audience, One Color." The award is issued annually for outstanding government publications by the National Association of Government Communicators. The final issue is attached to this Appendix.

Presentations

Table B-1 provides the number of presentations by year by the professional staff (including detailees) of the OAB, from November 1987 through December 1995. A total number of 217 presentations were given to approximately 16,000 people. Fifty-four presentations were given locally (in Washington DC or immediate area) to professional groups, agricultural commodity groups, public interest groups, high schools and colleges. Nationally, 128 presentations were given, while internationally 35 presentations were made.

Office Publications

The OAB staff undertook the drafting and publication of documents that were to provide guidance to USDA's biotechnology research community. These documents were widely distributed and were frequently cited in the scientific literature. They were:

1. Guidance for U.S. Researchers Involved in International Exchange on Agricultural Biotechnology. October 1989. 9 pg.
2. Agricultural Biotechnology: Introduction to Field Testing - March 1990. 58 pg.
3. Biotechnology at USDA. December 1990. 20 pg.

When the OAB published AGRICULTURAL BIOTECHNOLOGY: INTRODUCTION TO FIELD TESTING in March 1990 it recognized the importance of developing a mechanism to collect the biosafety data that would be generated by scientists world-wide that were involved in field testing. Hence, in conjunction with the Animal Plant Health Inspection Service (APHIS) and with participation of the Agricultural Biotechnology Research Advisory Committee (ABRAC), the OAB co-sponsored a series of symposia on the BIOSAFETY RESULTS OF FIELD TESTS OF GENETICALLY MODIFIED PLANTS AND MICROORGANISMS. The first international meeting of this series, at Kiawah Island, South Carolina in 1990, attracted 130 participants from 10 nations. The second international meeting, held in Goslar, Germany in 1992, attracted more than 200 participants from 22 nations. The third international symposium held in Monterey, California, , attracted more than 225 participants from 32 nations. Over the four years, an increasing number of participants were from developing nations, places where biosafety research is still, for the most part, in its infancy, but the potential opportunities from this emerging technology recognized! The diversity of cultures and tongues, as well as regulatory (i.e., biosafety) frameworks and unique field experiments was continued to stimulate requests for more information and more face-to-face dialogs. Thus, the proceedings of the series have been widely distributed in printed form, and in the case of the 3rd Proceedings they were placed into a file which could be accessed electronically.

Special Proceedings

The following Proceedings were paid for by the Office of Agricultural Biotechnology:

First International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms. November 27-30, 1990, Kiawah Island, South Carolina. David MacKenzie, Editor, 303 pg.

Abstracts of Papers Presented at the International Symposium on Applications of Biotechnology to Tree Culture, Protection, and Utilization. August 5-8, 1991, Columbus, OH, Forest Service General Technical Report NE-152. Bruce Haissig and Kent Kirk, Editors, 141 pg.

Conference Proceedings. Symbol, Substance, Science: The Societal Issues of Food Biotechnology. June 28-29, 1993, North Carolina Biotechnology Center, Research Triangle Park, N.C. W. Steve Burke, Editor, 146 pg.

Proceedings of the International Workshop on Animal Biotechnology Issues. April 1994, University of California, Davis, CA. Martina McGloughlin, Editor, 113 pg.

Proceedings of the 3rd International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms. November 13-16, 1994, Monterey, California. Daniel D. Jones, Editor, 558 pg.

Professional Publications

The lists of professional publications by Dr. Alvin Young, Dr. Daniel Jones, and Ms. Marti Asner are attached to this Appendix. Detailees are noted as authors or co-authors when appropriate.

TABLE B-1 Number of Presentations by year by the professional staff, including detailees, of the Office of Agricultural Biotechnology from November 1987 through December 1995.

<u>Years</u>	<u>Local</u> <u>(Washington DC Area)</u>	<u>National</u>	<u>International</u>
1987	5	8	0
1988	8	23	1
1989	7	14	2
1990	5	18	4
1991	4	15	11
1992	4	17	8
1993	10	7	3
1994	4	16	2
1995	7	10	4
Total -	<u>54</u>	<u>128</u>	<u>35</u>
Grand Total -			=217



United States
Department of
Agriculture

Cooperative
State Research,
Education and
Extension Service

Office of
Agricultural
Biotechnology

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20250-0904

DR. ALVIN L. YOUNG

Dr. Alvin L. Young is Director of the U.S. Department of Agriculture's (USDA) Office of Agricultural Biotechnology (OAB) and a Scientific Advisor to the Secretary of Agriculture. The Office reports to the Office of the Under Secretary for Research Education and Economics. It coordinates biotechnology programs throughout 10 USDA agencies and initiates cooperative activities with representatives from academic institutions and the biotechnology industry, as well as with policy leaders of the European Community and the Pacific Rim nations. In addition to directing activities of the office, Dr. Young also serves as Executive Secretary of the Agricultural Biotechnology Research Advisory Committee.

A native of Laramie, Wyoming, Dr. Young received his Bachelor and Master of Science degrees in Agricultural Sciences from the University of Wyoming. He earned his Ph.D. in Herbicide Physiology/Environmental Toxicology from Kansas State University. Dr. Young's career spans various research, academic, policy, and advisory positions with six Federal agencies and with the National Academy of Sciences. Prior to joining USDA, he was assigned to the Office of Science and Technology Policy, Executive Office of the President, as the Senior Policy Analyst for Life Sciences.

Dr. Young has conducted extensive research on the environmental, toxicological, and human health effects of pesticides for the Department of Defense. He served as Director of Research for Environmental Issues at the Veterans Administration. He was Associate Professor of Biological Sciences at the U.S. Air Force Academy, and a visiting Professor of Medical Genetics at the University of Colorado.

Dr. Young has authored many scientific books and articles on environmental issues, risk assessment, science policy, and biotechnology. He is currently Chairman of the White House Committee on Interagency Radiation Research and Policy Coordination. He represents USDA on the Biotechnology Research Subcommittee and the Committee on Health, Safety and Food, both components of the National Science and Technology Council. He is a member of NASA's Life and Microgravity Sciences Applications Advisory Committee. He strongly supports the transfer of technology from the public to the private sector.

1989 - 1990

PUBLICATIONS

ALVIN L. YOUNG

CHAPTER

1. Young, A. L. 1989. A White House perspective on risk communication. Chapter 12. P. 83-87. In: Covello, V. T., McCallum, D. B. and M. T. Pavlova (Eds.). Effective Risk Communication: The Role and Responsibility of Government and Nongovernment Organizations. Plenum Press, New York.
2. Young, A. L. 1990. Role of the Federal Government in agricultural biotechnology research and regulation. Chapter 20. P: 263-270. In: Vasil, I. K. (Ed.). Biotechnology: Science, Education and Commercialization. Elsevier Science Publishing Co., Inc., New York.
3. Cordle, M. K., J. H. Payne and A. L. Young. 1990. Regulation and oversight of biotechnological applications for agriculture and forestry. Chapter 14. P: 289-311. In: Ginzburg, L. R. (Ed.). Assessing Ecological Risks of Biotechnology - Butterworth-Heinemann Publishers, Stoneham, MA.
4. Gerber, J. F. and A. L. Young. In Press. Policy Issues in Biotechnology. Biomedical Engineering Monograph Series.

PROCEEDINGS

1. Young, A. L. 1989. Status of Agricultural Biotechnology. In: Annual Agricultural Outlook Conference, United State Department of Agriculture, Washington, DC. 14 p.
2. Young, A. L. 1990. The Committee on Interagency Radiation Research and Policy Coordination (CIRRPC). In: Tropical Symposium Proceedings: Environmental Radiation and Public Policy. Health Physics Society, Las Vegas, NV. 9 p.
3. Young, A. L. 1990. Coordination of Regulatory and Research Guidelines Affecting Biotechnology: An Overview. In: Risk Assessment in Agricultural Biotechnology: Proceedings of the International Conference. Cooperative Extension, University of California, Publication 1928, pp. 210-215.
4. Young, A. L. and M. B. Steinbock. 1990. The USDA Experience of Moving Agricultural Biotechnology into the Field. 5th European Congress on Biotechnology, Copenhagen, Denmark. 11 p.

9. Gerber, J. F. and A. L. Young. 1991. Social Implications of Transgenic Plants. In Kung, S. and D. D. Bills (Eds.). Biotechnology and Nutrition. Butterworth Publishers, Stoneham, MA.

Articles

1. Young, A. L. 1995. Biotechnology - Issues and Challenges. IEEE Engineering in Medicine and Biology 14(2):204-206.
2. Young, A. 1995. Guest Editorial. Sharing Data the Old Fashioned Way: Person to Person. Wisconsin BiolIssues 6(1):10.
3. Young, A. L. 1994. The Status of Federally-Funded Agricultural Biotechnology Research in the United States. Guest Editorial. Agro-Food-Industry Hi-Tech. 5(1-2):3-4.
4. Young, A. L. 1993. The Independent Study. ES&T. Guest Editorial Environ. Sci. Technol. 27(1):6.
5. Young, A. L. 1994. ABRAC Brickbats. Letter to the Editor. Bio/Technology 12:648.
6. Young, A. L. 1994. Biotechnology In China. BioScience 44(9):635-636.
7. Young, A. 1991. Agricultural Biotechnology - Challenges and Opportunities. Ag Biotechnology News 8(2):6&18.
8. Young, A. L. 1991. Who Will Reap the Rewards of Biotechnology? In Agricultural Research - Meeting the Challenges of the 1990's. Cornell University Press, Ithaca, NY pp. 171-178.
9. Young, A. L. and M. H. Madkour. 1991. A Perspective on Agricultural Biotechnology for Developing Countries. Proceedings. Transfer of Technology to Developing Countries, World Food Council. 3p.

LIST OF PUBLICATIONS

JONES, Daniel David

Jones, D.D., "Advisory Considerations on the Scientific Basis of the Food Safety Evaluation of Transgenic Animals," in *Animal Biotechnology and Ethics*, A. Holland and A. Johnson, eds., Chapman and Hall, London, in press.

Young, A.L. and Jones, D.D., "The Role of the Public and Federal Advisory Committees in Providing Advice to the Government on Agricultural Science Policy," *Genetically Modified Foods: Safety Aspects*, K.-H. Engel, G.R. Takeoka, and R. Teranishi, eds., American Chemical Society, Washington, D.C., 1995, pp. 52-58.

Jones, D.D. (editor), *Proceedings of the 3rd International Symposium on The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms*, University of California Division of Agriculture and Natural Resources, Oakland, CA, 1995.

Jones, D.D. and Cordle, M.K., "Prospects for the Genetic Manipulation of Dairy Cattle: Opportunities Beyond BST," *Biotechnology Advances*, 13, 235, (1995).

Jones, D.D. and Maryanski, J.H., "Safety Considerations in the Evaluation of Transgenic Plants for Human Food," in *Risk Assessment in Genetic Engineering*, M.A. Levin and H.S. Strauss, eds., McGraw-Hill, New York, 1991, pp. 64-82.

Jones, D.D., "Food Safety Aspects of Gene Transfer in Plants and Animals: Pigs, Potatoes, and Pharmaceuticals," *Food Drug Cosmetic Law Journal*, 42, 351, (1988).

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MARTI R. ASNER

PUBLICATIONS AND ARTICLES

1988-1996

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APPENDIX C

MEMBERSHIP

BIOTECHNOLOGY COUNCIL

AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE

**UNITED STATES DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY COUNCIL**

Name	Agency	Address	Telephone	FAX
Richard Parry (Chair)	ARS	Room 358A Jamie Whitten BG	202-720-3973	202-720-5427
Robert Faust		NPS, Room 338 Bldg. 005, BARC West	301-504-6918	301-504-6231
Karl Narang Alternate		NPS, Room 211, Bldg 005, BARC West	301-504-5771	301-504-5467
Ray Dobert (Ex Officio)		NAL, Biotech Info. Center, 4th Floor, Beltsville	301-504-5340	301-504-7098
John Payne (Vice-Chair)	APHIS	Room 2D15 4700 River Road(Unit 98) Riverdale, MD 20737	301-734-7602	301-734-8724
Arnold Foudin			301-734-7612	301-734-8669
Jim Cook	CSREES	Room 323 Aerospace Bldg. Washington, DC 20250-2200	202-401-5022	202-401-6438
Richard Frahm		Room 330-F, Aerospace	202-401-4895	202-401-4888
Ed Kaleikau Alternate		Room 323-E, Aerospace	202-401-1931	202-401-6438
John Reilly	ERS	Room 524, NRED, NYAVEBG/130 NY AVE, NW, Washington, DC 20005-4788	202-219-0450	202-219-0029 or 219-0477
Margriet Caswell, Alternate	ERS	Room 508, NRED/REP NYAVEBG	202-219-0507	202-501-6174
Calvin F. Bey	FS	Auditors Bldg., 1st Floor, N.W. Washington, DC	202-205-1178	202-205-1551
James L. Stewart Alternate		Auditors Bldg, 1st Floor, SW	202-205-1532	202-205-6207
Pat Basu	FBI	Room 302-Cotton Annex Bldg	202-720-8623	202-720-0582
Ann McNamara Alternate		409 Annex Bldg Washington, DC 20250	202-205-0212	202-720-4662
William Franks, Jr.	AMS	Room 3507-S	202-720-5231	202-720-6496
Alan R. Post Alternate			202-720-3322	202-720-6496
Alvin L. Young, Executive Secretariat	OAB	Room 3868-3 Washington, DC 20250-0904	202-720-5853	202-720-5336

November 28, 1995

U.S. Department of Agriculture		Date Submitted: January 31, 1996		Under Secretary Research, Education & Economics Office of Agricultural Biotechnology	
COMMITTEE RECORD		Committee: Agricultural Biotechnology Research Advisory Committee			
Membership 1994-1996					
Members Full Name: Title:		Organization	Area of Expertise	Term	
Lauderdale, James		The Upjohn Company	Veterinary/Animal Science	1992/1996	
Osorio, Fernando		Dept. of Veterinary & Biomedical Sciences University of Nebraska	Veterinary/Animal Science	1994/1996	
Kapuscinski, Anne R.		Dept. of Fisheries and Wildlife University of Minnesota	Veterinary/Animal Science	1992/1996	
Hill, Walter A. , <u>Chair</u>		Tuskegee University	Plant Science	1992/1996	
Fuchs, Roy		Monsanto Agricultural Company	Plant Science	1994/1996	
Sederoff, Ronald R.		Dept. of Forestry North Carolina State University	Plant Science	1992/1996	
Wood, H. Alan		Boyce Thompson Institute for Plant Research	Plant Science	1994/1996	
Marrone, Pamela G.		Novo Nordisk Entotech, Inc.	Entomology	1992/1996	
Harlander, Susan		Land O'Lakes	Microbiology/Food Science	1992/1995	
Woo, Robin		Georgetown University	Microbiology/Food Science	1995/1996	
Wodzinski, Rudy		Dept. of Molecular Biology & Microbiology	Microbiology/Bioprocessing	1992/1996	
Letourneau, Deborah K.		Board of Environmental Studies University of California	Ecology/Environmental Science	1990/1996	
Tiedje, James		NSF Center for Microbial Ecology Michigan State University	Ecology/Environmental Science	1994/1996	
Reid, Walter		World Resources Institute	Environmental/Public Policy	1994/1996	
Pierce, Stanley		Rivkin, Radler, Bayh, Hart, & Kremer	Biotechnology Law/Regulation	1992/1996	
Thompson, Paul		Center for Biotechnology Policy & Ethics Texas A&M University	Bioethics	1994/1996	

U.S. Department of Agriculture	Date Submitted: January 29, 1993	Assistant Secretary for Science and Education, Office of Agricultural Biotechnology	
COMMITTEE RECORD	Committee: Agricultural Biotechnology Research Advisory Committee		
Membership: 1992-1993			
Members Full Name: Title:	Organization	Area of Expertise	Term
Andow, David A. Associate Professor, Entomology	University of Minneosta	Ecology	1990/1994
Bruggemann, Edward P. Staff Scientist	National Audubon Society	Environmental Policy	1992/1994
Fraley, Robert T. Director	Monsanto Company	Plant Science	1992/1994
Harlander, Susan Director, Research & Development	Land O'Lakes	Microbiology/Food Science	1992/1994
Hill, Walter A. Professor, Dean & Research Director	Tuskegee University	Plant Science/Agronomy	1992/1994
Kapuscinski, Anne R. Associate Professor	University of Minnesota	Animal Science/Fisheries	1992/1994
Kline, A. David, Chair Professor and Dean	State University of New York	Bioethics/Environmental Policy/Public Attitudes	1990/1994
Lauderdale, James Director and Senior Scientist	The Upjohn Company	Animal Science	1992/1994
Letourneau, Deborah K. Associate Professor	University of California - Santa Cruz	Ecology	1990/1994
Marrone, Pamela G. President	Endotech, Inc.	Entomology	1992/1994
Pierce, Stanley Ph.D., J.D.	Rivkin, Radler, & Kramer	Biotechnology Law/Regulation	1992/1994
Sederoff, Ronald R. Professor of Forestry	North Carolina State University	Plant Science/Forestry	1992/1994
Vidaver, Anne K. Professor and Chair	University of Nebraska	Microbiology/Plant Pathology	1990/1994

U.S. Department of Agriculture		Date Submitted: January 29, 1993		Assistant Secretary for Science and Education, Office of Agricultural Biotechnology	
COMMITTEE RECORD		Committee: Agricultural Biotechnology Research Advisory Committee			
Membership: 1992-1993					
Members Full Name: Title:		Organization	Area of Expertise	Term	
Wodzinski, Rudy J. Professor, Molecular Biology & Microbiology		University of Central Florida	Microbiology	1992/1994	
Witt, William Director		Food & Drug Administration	Animal Science/Veterinary Medicine	1992/1994	

U.S. Department of Agriculture	Date Submitted: January 29, 1993	Assistant Secretary for Science and Education, Office of Agricultural Biotechnology	
COMMITTEE RECORD	Committee: Agricultural Biotechnology Research Advisory Committee		
Membership 1990-1991			
Members Full Name: Title:	Organization	Area of Expertise	Term
Andow, David A. Professor	University of Minnesota	Ecology	1990/1992
Bollinger, William H. Vice President	Terra Tek, Inc.	Plant Science	1990/1992
Bulla, Lee Professor	University of Wyoming	Microbiology	1990/1992
Hafs, Harold Vice President	Merck, Sharp & Dohme Research Labs	Animal Science/Veterinary Medicine	1988/1992
Hill, George C. Professor	Meharry Medical College	Biochemistry/Parasitology	1990/1992
Kemp, John D. Director	New Mexico State University	Plant Science	1988/1992
Kline, A. David Professor	State University of New York	Bioethics/Environmental Policy/Public Attitudes	1990/1992
Korwek, Edward Partner - Hogan & Hartson	Hogan & Hartson	Biotechnology Law/Regulation	1988/1992
Letourneau, Deborah Professor	University of California	Ecology	1990/1992
Osburn, Bennie L. Chair Associate Dean-Research	University of California	Animal Science/Veterinary Medicine	1988/1992
Sorensen, A. Ann Assistant Director	Amercian Farm Bureau Federation	Entomology	1988/1992
Tolin, Sue A. Professor	VPI and State University	Microbiology/Plant Pathology	1988/1992
Vidaver, Anne K. Professor	University of Nebraska	Microbiology/Plant Pathology	1990/1992
Whitmore, F. William Professor	Ohio State University	Plant Science/Forestry	1988/1992

Witt, William Professor	Food & Drug Administration	Animal Science/Veterinary Medicine	1990/1992
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Members Full Name: Title:	Organization	Area of Expertise	Term	
Osburn, Bennie I., Chair Associate Dean-Research	School of Veterinary Medicine, U of CA-Davis	Animal Science/Veterinary Medicine	1988/1991	
Hafs, Harold D. Vice President, Animal Science Research & Development	Merck, Sharp & Dohme Research Labs	Animal Science/Veterinary Medicine	1988/1991	
Gorham, John R. Research Leader, Animal Diseases Research Unit	Washington State University	Animal Science/Veterinary Medicine	1988/1990	
Sorensen, A. Ann Assistant Director, N.E.R. Division	American Farm Bureau Federation	Entomology	1988/1990	
Gould, Fred Insect Ecologist & Geneticist	North Carolina State University	Ecology/Environmental Science	1988/1990	
Whitmore, F. William Professor	Ohio State University	Plant Science/Forestry	1988/1991	
Frey, Nicholas M. Director, Technology Acquisition & Development	Pioneer Hi-Bred International	Plant Science	1988/1990	
Kemp, John D. Lead Scientist/Director	New Mexico State University	Plant Science	1988/1991	
Tolin, Sue A. Professor	VPI and State University	Microbiology/Plant Pathology	1988/1991	
Bothast, Rodney Research Leader/Microbiologist	Northern Regional Research Lab., ARS	Industrial Microbiology/Bioprocessing	1988/1990	
Korwek, Edward Partner - Hogan & Hartson	Hogan & Hartson	Biotechnology Law/Regulation	1988/1991	
Hollander, Anne K. Associate	The Conservation Foundation	Environmental Policy	1988/1990	
Phaire-Washington, Linda Associate Director, Carver Research Foundation	Tuskegee University	Immunology/Virology/Cell Biology/Biochemistry	1988/1990	

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